



# European Court gives narrow protection to DNA-based biotech patents

## Summary and implications

On 6 July 2010 the Court of Justice (the renamed European Court of Justice) delivered its first-ever judgment on the extent of protection that European patents should give to biotech patents.<sup>1</sup> It held that Monsanto cannot prevent soy meal being sold in the EU that contains, in a residual state, a DNA sequence patented by it.

This judgment is significant for a number of reasons. It marks a significant restriction on the powers biotech companies can wield with their patents. It also provides Europe's answer to the classic DNA conundrum of where to set the boundaries of protection.

This is the first time the Court of Justice has been able to consider the scope of the protection of biotech inventions, particularly DNA sequence patents, in the ten years the EU Biotechnology Directive has been in force. In a rare move intended to give extra weight to this judgment, the Court of Justice sat as a nine judge Grand Chamber.

- The Court has given a narrow interpretation to the Biotechnology Directive. It roundly rejected Monsanto's argument that it should be entitled to the broadest possible protection to its Roundup Ready patent (i.e. to its DNA sequence as such).
- It held instead that the protection given to DNA sequence patents should be 'purpose-bound'. No protection should be given to patented DNA sequences where they are not performing the specific function for which they were patented (in the case of Monsanto's Roundup Ready soya, this function is protecting the plant against the effects of a herbicide).
- This result severely curtails the protection of DNA sequence patents, as it means that no derivative or processed products will be protected if they fall outside the scope of what the patent expressly states the function of the DNA sequence to be.
- The result of this judgment is that DNA patents will not be given a disproportionate and overly wide level of protection. Patent owners will not be able to lay claim over an unspecified number of derivative products coming under their control. Patent owners must now pay close

## Ask a question

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<sup>1</sup> *Monsanto Technology LLC v. Cefetra BV & Others*, Case C-428/08

attention in future patent applications to how they specify the function of their DNA sequences.

### **Practical points – likely impact for clients**

A number of points should be noted:

#### **a) Are DNA-based patents now less valuable in the EU?**

It would be wrong to assume that this defeat for Monsanto means that protection for biotech patents in the EU is somehow diminished. The opposite is in fact the case. They are as valuable and as available as ever. This judgment affirms the principles established in the Biotechnology Directive – provided biotech patents properly explain the function to be performed by their genetic information, patentees will be able to get commensurately broad and strong patents.

The context is important in explaining why the Court ruled as it did. Monsanto was seeking to broaden the scope of protection for its patent beyond the terms of the Directive and potentially into processed and derivative products, which was too remote from the function claimed by its patent.

#### **b) Patentees**

The European Patent Office has indicated it will apply this decision, even though it is not formally bound by Court of Justice decisions. This means that applicants must give careful consideration to drafting their patent applications to ensure that the function to be performed is as broad as possible whilst not giving third parties ammunition to invalidate patents granted subsequently.

#### **c) Third parties**

The emphasis given by the Court of Justice on function when assessing the scope of protection sends a clear signal that third parties (whether opposing in the EPO or engaged in litigation) must examine the stated function very closely. This can give rise to absolute arguments that the function in dispute is not a patentable invention, as well as to arguments that the use or product in issue does not constitute an infringement.

### **Factual background**

The case arises from Monsanto's attempt to prevent Argentinean soy meal (containing the DNA sequence protected by Monsanto's Roundup Ready soybeans patent) being imported into the EU. This DNA sequence makes soybean plants resistant to the Roundup Ready herbicide, allowing farmers to use high levels of herbicide to produce greater yields.

The patent covers DNA sequences encoding a class of enzyme variants resistant to this herbicide. These can be introduced into soybean plants to replace the non-resistant native form of the enzyme (which would otherwise be affected by the herbicide, killing the plant).

Cefetra imported soy meal from Argentina made from plants expressing the patented DNA. Monsanto had no Argentine patent and so could not

argue that cultivation of these Argentine plants was an infringement. Monsanto therefore sued Cefetra and the other importers of this Argentine soy meal in the Netherlands based on the Biotechnology Directive.

### Must a DNA sequence "currently" perform its patented function?

The Court was asked whether Monsanto's Roundup Ready DNA sequence should be protected even though the DNA sequence was not performing its patented function (protecting plants from Roundup) at the time of the alleged infringement (the act of importation as soy meal), but had previously done so (as a plant), and was capable of performing that function again (the meal can potentially be used to create such plants again).

The Court held that the function of Monsanto's DNA sequence is to protect the soya plant against the effect (or possible effect) of a herbicide which can kill the plant. Importantly, the DNA sequence cannot perform this function if the genetic information can be found only in a residual state in the soy meal, as this is a dead material obtained after the soy has undergone several treatment processes.

Monsanto attempted to argue for as broad as possible a meaning of "function", in that its DNA sequence in the soy meal had previously performed this protective function in plants, and could potentially be used to create such plants again. This was roundly dismissed. The Court held that such an argument would emasculate the Directive, since one or other of those situations could, in principle, always be present. The Court's reasoning was as follows:

- Recital 23 of the Directive provides that a mere DNA sequence with no stated function contains no technical information and is not therefore a patentable invention;
- The combination of Recital 23 and Article 5(3) means that DNA sequences get no patent protection when the function performed by that sequence is not specified;
- Because the Directive makes the patentability of a DNA sequence subject to the specified function it performs, the Directive must be interpreted as not giving protection to a patented DNA sequence which is not able to perform the specific function for which it was patented. The Court found support for this in Article 9, which provides that a patent based on genetic information is subject to the condition that the genetic information performs its function in the material in which it is incorporated.

Patent protection will therefore only be given to DNA sequences where the DNA sequence is currently expressing its function. DNA sequences will only be protected where they perform the function for which they were patented, i.e. the protection conferred on DNA sequences is a 'purpose-bound' protection. Monsanto's patent was not infringed because its DNA sequence was not performing its function when it is incorporated in a dead material such as soy meal.

#### Recital 23 and Article 5(3)

- Recital 23: Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention
- Article 5(3): The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

#### Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material ... in which the product is incorporated and in which the genetic information is contained and performs its function.

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